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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/687,897

10/17/2003

Antonella Pesce

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9804

27752 7590 10/19/2007
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EXAMINER

BETTON, TIMOTHY E

ART UNIT	PAPER NUMBER
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1614

MAIL DATE	DELIVERY MODE
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10/19/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/687,897

Applicant(s)

PESCE ET AL.

Examiner

Timothy E. Betton

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 1,3,4,6,9,10,13,15 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 2,5,7,8,11,12,14, and 17-19 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicants Amendments and Remarks filed 6 August 2007 have been acknowledged and made of record. In reconsideration of the previous Requirement for Restriction, it may not have been entirely made clear that a single disclosed specie of ketal is required for disclosure in instant invention for further examination.

Supplemental Action

Claims 1-19 are pending. Claims 1, 3, 4, 6, 9, 10, 13, 15, and 16 are withdrawn from further consideration. Claims 2, 5, 7, 8, 11, 12, 14, and 17-19 are pending for examination on the merits, of which all pending claims as cited for examination are all also currently amended.

Applicants were initially required to make an election of species based on the Office Action mailed 5 July 2007. However, upon further reconsideration, in addition to responding to the required species election in accordance to said Office Action, applicant is further required to make a species election from claims 2 and 8.

Election of ketal species from claim 2

Applicants are required to elect a specific ketal moiety from the list cited in instant claim 2. A specific chemical and/or chemical group is required for each and every disclosed R-substituent, i.e., (R1 –R3). For example, where R1 represents a C2-C6 alkylene radical, R2 represents a C1-C10- alkyl, and where R3 represents a C5-C7-cycloalkyl.

Election of Species for an emollient from claim 8

Applicant is also required to elect one, specific, and exact emollient according to instant claim 8 selected from: (1) petroleum-based; (2) sucrose ester fatty acids; (3) polyethylene glycol

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and derivatives thereof; (4) fatty acid ester type; (5) alkyl ethoxylate type; (6) fatty acids, (7) fatty acids, particularly those having from about 8 to about 28 carbon atoms in their fatty chain; (8) fatty acid ester ethoxylates; (9) fatty alcohol type; (10) polysiloxane type; (11) propylene glycol and (12) derivatives thereof; (13) glycerine and (14) derivatives thereof, including (15) glyceride, (16) acetoglycerides, and (17) ethoxylated glycerides of C8-C28 fatty acids; (18) spermaceti and (19) other waxes; (20) fatty alcohol ethers, (21) fatty alcohol ethers, particularly those having from about 8 to about 28 carbon atoms in their fatty chain, (22) propoxylated fatty alcohols; (23) other fatty esters of polyhydroxy alcohols; (24) lanolin and (25) its derivatives; (26) kaolin and (27) its derivatives; (28) sorbitol and (30) its derivative; (31) trihydroxy stearin; (32) ester derivatives and (33) mixtures thereof.

Election of Species Requirement

Instant applications disclose claims directed to the following patentably distinct species of **(a)** one specific and exact ketal compound moiety of the disclosed formula (claim 2) and **(b)** one specific and exact emollient (claim 8).

The species are independent and distinct because:

The species recited in the present claims 2 and 8 are structurally and chemically distinct. They are structurally or chemically distinct from each other, such that a comprehensive search of the patent and non-patent literature for a specific ketal moiety would not readily result in a comprehensive search for a specific emollient species of any one of instant claims 2 and 8 and/or more of the other distinct species groups cited in instant claims 2 and 8, respectively. Applicant may have established an underlying common function to this broad genus of agents, namely, that they are capable and/or reasonably indicated as constituents in a delivery system via an article

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suitable to be worn in contact with mammal body, it remains that the art does not necessarily recognize such a shared function as being common to each of the variety of distinct species of claim 2 in regard to claim 8. Furthermore, the disparate nature and variability encompassed by each said claim in view to their own respective broad genus disclosures, precludes a quality examination on the merits not only because a burdensome search would be required for the entire scope of the claims 2 and 8, but also because consideration of the findings of such a search for compliance with the statutes and requirements set forth under 35 U.S.C. 101, 102, 103 and 112 would be an undue burden. In addition, the discovery of any one of the presently claimed species would not necessarily anticipate or reasonably suggest or render obvious the use of the other distinct species claimed for the same objective.

Election of species should be made consistent with the following instructions:

(i) Applicants are required to elect a single disclosed species of (a) one specific and exact ketal moiety species of disclosed formula (claim 2) and (b) a specific emollient species (claim 8).

Applicant is cautioned that the election of a particular combination of species, wherein the elected combination of agents is not adequately supported by the accompanying specification, may raise an issue of new matter under the written description requirement of 35 U.S.C. 112, first paragraph.

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Applicant is also reminded that a proper reply to this election will include the identification of the exact page and line number that supports the elected specie(s).

Currently, claims 2, 5, 7, 8, 11, 12, 14, and 17-19 are generic in claimed invention.

Applicant is advised that a reply to this requirement must include an identification of the species that are elected consonant with this requirement and a listing of all claims readable thereon the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, Applicant must indicate which are readable upon the elected species. Please reference MPEP §809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though this requirement be traversed (37 C.F.R. 1.143) and (ii) an identification of the claims encompassing the elected species.

The election of species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species, the election shall be treated as an election without traverse.

Should Applicant traverse on the ground that the species are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds the invention unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Transitional Period (10/14/2007-11/10/2007)

Effective November 1, 2007, if applicant wishes to present more than 5 independent claims or more than 25 total claims in an application, applicant will be required to file an examination support document (ESD) in compliance with 37 CFR 1.265 before the first Office action on the merits (hereafter "5/25 claim threshold"). See Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications, 72 Fed. Reg. 46715 (Aug. 21, 2007), 1322 Off. Gaz. Pat. Office 76 (Sept. 11, 2007) (final rule). The changes to 37 CFR 1.75(b) apply to any pending applications in which a first Office action on the merits (FAOM) has not been mailed before November 1, 2007. Withdrawn claims will not be taken into account in determining whether an application exceeds the 5/25 claim threshold. For more information on the final rule, please see <http://www.uspto.gov/web/offices/pac/dapp/opla/presentation/clmcontfinalrule.html>.

In response to the restriction requirement set forth in this Office action, applicant is required to file an election responsive to the restriction requirement. Applicant may not file a suggested restriction requirement (SRR) in lieu of an election responsive to the restriction requirement as a reply. A SRR alone will not be considered a *bona-fide* reply to this Office action.

If applicant elects an invention that is drawn to no more than 5 independent claims and no more than 25 total claims, applicant will not be required to file an ESD in compliance with 37 CFR 1.265 that covers each of the elected claims. If the elected invention is drawn to more than 5 independent claims or more than 25 total claims, applicant may file an amendment canceling a number of elected claims so that the elected invention would be drawn to no more than 5 independent claims and no more than 25 total claims.

If the restriction requirement is mailed on or after November 1, 2007, applicant is also required to file an ESD in compliance with 37 CFR 1.265 that covers each of the elected claims, unless the elected invention is drawn to no more than 5 independent claims and no more than 25 total claims taking into account any amendment to the claims. To avoid the abandonment of the application, the ESD (if required) and the election must be filed within **TWO MONTHS** from the mailing date of this Office action. The two-month time period for reply is extendable under 37 CFR 1.136.

If the restriction requirement is mailed before November 1, 2007, the election must be filed within **ONE MONTH** or **THIRTY DAYS**, whichever is longer, from the mailing date of this Office action. The time period for reply is extendable under 37 CFR 1.136. Furthermore, if the elected invention is drawn to more than 5 independent claims or more than 25 total claims taking into account any amendment to the claims, the Office will notify applicant and provide a time period in which applicant is required to file an ESD in compliance with 37 CFR 1.265 covering each of the elected claims or amend the application to contain no more than 5 independent elected claims and no more than 25 total elected claims.

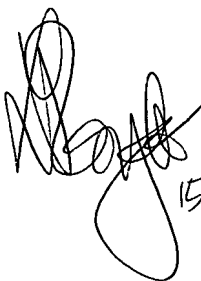
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy E. Betton whose telephone number is (571) 272-9922. The examiner can normally be reached on Monday-Friday 8:30a - 5:00p.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TEB



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SUPERVISORY PATENT EXAMINER